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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WORLEY, CATHY KINGDON	
ART UNIT	PAPER NUMBER
1638	
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12/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,742	FOGHER, CORRADO	
	Examiner	Art Unit	
	CATHY K. WORLEY	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *5-12 and 15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 13, and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed Sept. 28, 2009, has been entered.

2. Claims 1-20 are pending.

Claims 5-12 and 15-20 are withdrawn.

3. Claims 1-4, 13, and 14, as they relate to SEQ ID NO:36, are examined in the present office action.

Rejections and Objections that are Withdrawn

4. The objections to the abstract and title are withdrawn in light of the Applicant's amendments to the abstract and title

5. The rejection of claims 1-4, 13, and 14 under 35 USC 112, first paragraph, for lack of written description is withdrawn in light of the Applicant's amendments to the claims.

6. The rejection of claims 1 and 4 under 35 USC 103(a) over Sangtong V. in view of Schuhmann and further in view of Whitelam is withdrawn in light of the Applicant's amendments to the claims.

Claim Objections

7. Claims 1-3 are objected to because of the following informalities: they continue to recite non-elected proteins and sequences. In the response received on Aug. 29, 2008, the Applicant elected to prosecute SEQ ID NO:36 which corresponds to 1Bx7. No linking claim is found to be allowable, and a storage protein comprising SEQ ID NO:11 does not, in fact, link all of the recited proteins; therefore, the non-elected proteins and sequences will not be examined in this case. The Applicant is advised to delete all recitations of non-elected proteins and sequences. Appropriate correction is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Amended claims 1-4, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangtong, V. (Dissertation (2001) from Iowa State University) in view of Benmoussa et al (WO 00/18927, published on April 6, 2000), further in view of Arentz-Hansen et al (J. Exp. Med. (2000) Vol. 191; pp. 603-612), further in view Schuhmann, F. (US Patent No. 6,517,874, issued on Feb. 11, 2003, and published as US Pre-Grant Publication US 2002/0061344 on May 23, 2002), and further in view

of Whitelam, G. C. (J. Sci. Food Agric. (1995) Vol. 68, pp. 1-9). This new rejection is necessitated by the Applicant's amendments to the claims.

The amended claims are directed to a flour which is derived from the seed of a plant expressing transglutaminase and one or more genes coding for wheat storage proteins; and further comprising a mutagenized SEQ ID NO:36 which corresponds to 1Bx7.

Sangtong teaches transgenic corn expressing the wheat storage protein, gluten 1Dx5, (see entire document). Sangtong teaches that bread-making quality of tritordeum was significantly improved by transforming it to express the storage proteins 1Ax1 and 1Dx5 from wheat (see second paragraph on page 11). Sangtong states that "we would like to make maize with novel flour property. The Glu-1Dx5 gene encoding for 1Dx5 HMW glutenin subunit that contributes elasticity to wheat dough was transformed into maize. … We will study the effect of 1Dx5 HMW glutenin subunit on maize flour property." It is known in the art that some people are allergic to wheat products (known as Celiac's disease); therefore, the corn flour made from the transgenic maize that is taught by Sangtong would have been less allergenic that wheat flour.

Sangtong does not teach seeds of plants expressing transglutaminase nor does Sangtong teach plants expressing a protein comprising a mutagenized SEQ ID NO:36.

Benmoussa et al teach transgenic potato plants expressing wheat glutenin (see page 15). They specifically suggest multiple wheat storage proteins could be expressed in multiple starchy plant tissues; including the storage proteins glutenin, gliadin, albumin, and globulin (see abstract) and specifically including expression in maize (see abstract). They teach that the flours obtained by these starchy plants that have been transformed to express these wheat storage proteins can be used in applications that require increased viscosity and heat stability, and they specifically indicate that they are suitable for pastry- or bread-making (see entire document and page 10, lines 20-23).

Arentz-Hansen et al teach mutagenesis of gliadin to render the gliadin less immunogenic; specifically generating synthetic peptides with a lysine residue substituted for the glutamine residue at position 63 or 65 of a peptide comprising PFPQPQLPY (same as the instant SEQ ID NO:36); and position 65 corresponds to position 6 in the instant SEQ ID NO:36 (see page 608 and Figure 4A). Arentz-Hansen et al teach that this epitope is commonly recognized by the T-Cells of Celiac Disease patients (see page 608, right column).

Schuhmann teaches the addition of transglutaminase to flours, especially flours with low wheat content, to improve their dough properties, including retention of gas in the dough to result in an increase in bread volume (see column 2). Schuhmann teaches that the transglutaminase enzyme may be produced recombinantly (see column 4, lines 4-5).

Whitelam teaches that enzymes that are useful for processing of plant material can be produced recombinantly in the plants themselves (see introduction and pages 6 - 7). Whitelam specifically uses amylase and phytase as examples of such enzymes. In both of these cases the enzymes have traditionally been added to the plant material, but the experiments showed that they were successful in producing amylase and phytase in transgenic plants such that no exogenous enzyme would be required for processing (see pages 6-7).

At the time the invention was made, it would have been obvious and within the scope of one of ordinary skill in the art to modify the flours taught by Sangtong and Benmoussa et al to utilize transgenic seeds that expressed mutagenized gliadin that had reduced allergenicity for Celiac disease patients compared to wild-type gliadin. One would have been motivated to do so, because Arentz-Hansen et al teach that Celiac disease is the most common food sensitivity in humans (see introduction), and they specifically teach that substituting a lysine for the glutamine at the position that corresponds to position 6 in the instant SEQ ID NO:36 is a substitution that eliminates T-Cell binding. Therefore, one of ordinary skill in the art would have appreciated that utilizing a gliadin coding sequence that was mutagenized to substitute lysine for glutamine at this position would have resulted in reduced allergenicity of the resulting flour for people with Celiac disease.

Benmoussa et al teach that glutenins and gliadins form inter-molecular cross-links that create a proteinaceous matrix which provides bread dough with viscoelastic properties (see lines 15-17 on page 1). Shuhmann teaches that transglutaminase generates new connections be the amino acids glutamine and lysine that are contained in the flour protein (see column 2, lines 55-58). At the time the invention was made, it would have been obvious and within the scope of one of ordinary skill in the art to combine the teachings of Benmoussa et al and Arentz-Hansen et al with the teachings of Shuhmann and Whitelam to arrive at transgenic maize plants expressing both transglutaminase and a mutagenized gliadin. One would have been motivated to utilize the mutagenized gliadin for the reasons discussed above. One would have been motivated to include transglutaminase because Shuhmann teaches that adding transglutaminase to low-wheat flours improves the properties of dough made from such flours, and Whitelam teaches that one can grow processing enzymes in transgenic plants so that one would not have to add exogenous enzymes to the plant material for processing. One of ordinary skill in the art would have appreciated that by including expression of recombinant transglutaminase in the seeds that are also expressing gliadin, one would have been able to produce flour with improved dough properties that would not require addition of wheat or addition of transglutaminase enzyme.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHY K. WORLEY whose telephone number is (571)272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00, with additional variable hours before 10:00 and after 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Cathy K. Worley/
Primary Examiner, Art Unit 1638